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DENTSPLY

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DATE PREPARED: April 2, 1996

TRADE OR PROPRIETARY NAME:

FINESSE™ LOW-FUSING PORCELAIN SYSTEM AUXILIARY PRODUCTS

CLASSIFICATION NAME: Porcelain Powder for Clinical Use 872.6660

PREDICATE DEVICE: Finesse™ Low-Fusing Porcelain System K954761

DEVICE DESCRIPTION: The **FINESSE™ LOW-FUSING PORCELAIN SYSTEM AUXILIARY PRODUCTS** contain mixtures of frits, opacifiers and pigments in varied quantities to create an assortment of materials with a variety of fusion temperatures, translucencies and colors. They contain the same silicate frits and opacifiers, and some of the same pigments used in K954761. Additional pigments used are also used in predicate medical devices.

The physical properties for **FINESSE™ LOW-FUSING PORCELAIN SYSTEM AUXILIARY PRODUCTS** meet the appropriate ISO Standards.

INTENDED USE: The **FINESSE™ LOW-FUSING PORCELAIN SYSTEM AUXILIARY PRODUCTS** are for use with the Finesse™ Low-Fusing Porcelain System in conjunction with non-precious or noble or high noble alloys when used for conventional porcelain-fused-to-metal crowns, bridges or dental prostheses.

TECHNOLOGICAL CHARACTERISTICS: The **FINESSE™ LOW-FUSING PORCELAIN SYSTEM AUXILIARY PRODUCTS** consist of opaque modifiers, opaque correction, dentin correction and stains, and glaze porcelains. These porcelains are substantially equivalent to Finesse Low-Fusing Porcelains (K954761).

All of the components in the **FINESSE™ LOW-FUSING PORCELAIN SYSTEM AUXILIARY PRODUCTS** have been used in predicate medical devices.

We believe that the prior use of the **FINESSE LOW-FUSING PORCELAIN SYSTEM AUXILIARY PRODUCTS** components in predicate devices, the performance data, and the results of toxicity testing on the predicate device, support the safety and effectiveness of **FINESSE LOW-FUSING PORCELAIN SYSTEM AUXILIARY PRODUCTS** for the intended uses.

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